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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,037	10/27/2000	Peter Bennett Duff Whyte	U013032-6	8344
140 7590 02/07/2011 LADAS & PARRY LLP 1040 Avenue of the Americas NEW YORK, NY 10018-3738				
EXAMINER WARE, DEBORAH K				
ART UNIT 1651		PAPER NUMBER		
NOTIFICATION DATE 02/07/2011		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

[nyuspatactions@ladas.com](mailto:nyuspatactions@ladas.com)  
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**Office Action Summary****Application No.**

09/702,037

**Applicant(s)**

WHYTE, PETER BENNETT DUFF

**Examiner**

DEBBIE K. WARE

**Art Unit**

1651

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/15/10.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28-39, 46 and 75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-39, 46 and 75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-85/06)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s) Mail Date \_\_\_\_\_

### **DETAILED ACTION**

Claims 28-39, 46 and 75 are presented for reconsideration on the merits.

#### ***Response to Amendment***

The amendment filed November 15, 2010, and extension of time have been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The rejections under 35 USC 112, first and second paragraphs have been removed.

#### ***Foreign Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Australia on April 30, 1998. It is noted that applicant has filed on June 5, 2006, a certified copy of the patent application as required by 35 U.S.C. 119(b).

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28-39, 46 and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by 282898, cited on a previously submitted PTO-1449 Form .

Claims are drawn to a colostrum fraction which can improve work performance once ingested.

The reference 282893 teaches preparing a colostrum fraction which can improve exercise. See pages 4-5, lines 1-25 and 10-25. Also see page 9, wherein ultrafiltration is carried out, see line 13. Note Table 1, the casein is contained in the fraction along with IGF-1, see page 18. Spray drying (page 9, line 25) is also carried out after ultrafiltration steps (page 9, line 19) to obtain the fraction. The heating temperature is less than 72 and 64 degrees centigrade. Centrifugation (e.g. flow-through) is disclosed.

The claims are identical to the cited disclosure of 282893 and are, therefore, considered to be anticipated by the teachings therein. All of the same steps are used to prepare the fraction and it contains IGF-1, and casein; thus it will have the ability of improving work performance since it is the same composition as claimed.

Throughput and residence time control during centrifugation are inherent to the teachings because the reference clearly discloses specified rates for centrifugation. Note page 14, lines 20-28. Also bacterial reduction will necessarily occur as a result of the disclosed centrifugation. Furthermore, since the heating occurs before centrifugation the temperature of 90 degrees centigrade will drop below 72 degrees centigrade, especially since temperatures below 64 degrees centigrade are disclosed to be desirable, note page 7, line 9. Improvement in bone deficiencies will promote the ability to do more exercise by an individual (e.g. human) ingesting the disclosed fraction.

Also the composition of the reference 282893 at page 20, line 1, is disclosed to contain 0.5 which is about 1 weight percent amount being administered. Hence about 0.5 to 1 gram per kg per day ingested are within the weight percent amount being ingested by the subjects of the cited disclosure.

The colostrum study is conducted over a period of at least four weeks, therefore, for the experimental subjects to ingest daily over a period of at least four weeks is disclosed, in accordance with the protocol described for the disclosed reference. In addition, to walking will be improved by improving the bone mass of an individual. Also improved bone mass will improve body mass and stature. Therefore, the claims are considered to be anticipated by the cited reference.

### ***Response to Arguments***

Applicant's arguments filed November 15, 2010, have been fully considered but they are not persuasive. The technical field disclosure teaches the two claimed steps for preparing a colostrum fraction, ultrafiltration and spray drying, see Example 7, line 18 and line 20, wherein a composition containing IGF-1, is obtained. Applicants' claims do contain IGF-1 as well in the colostrum fraction. A colostrum sample, as disclosed by the reference, and subjected to the identical steps of ultrafiltration and spray drying will yield a composition as claimed because in the eluate an amount of colostrum will still be present. Thus, a powdered composition containing IGF-1 is identical to a colostrum fraction as claimed because Applicants' own specification teaches that the composition is a powder, note page 8, line 8. Furthermore, by Applicants' own admission the reference uses their composition for improving physical work, see the response at page 6, last 3 lines. Therefore, the reference does not just use IGF-1 it uses a composition containing IGF-1 to improve physical work. The claims read on such a composition containing IGF-1 because the same process steps are practiced on colostrum and a powdered composition containing IGF-1 is obtained. Improved bone mass will

inherently improve body mass and stature as well as walking. The rejection is, therefore, sustained.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Deborah K. Ware/

Deborah K. Ware

Primary Examiner, AU 1651